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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,457	03/09/2001	Nonda Katopodis	NK3	7046

7590 10/22/2002

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/802,457

Applicant(s)
Katopodis

Examiner
Karen Canella

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Response to Amendment

1. Claims 1, 6, 17 and 18 have been amended. Claims 19 and 20 have been added. Claim 1-20 have been amended and are under consideration.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

3. Claims 19 and 20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 17 and 18 are drawn to the analysis of a subject's cerebral spinal fluid, saliva or sputum. Claims 19 and 20 are drawn to the analysis of a subject's peritoneal fluid, pleural fluid, or bronchial washings. Claims 19 and 20 cannot be dependent on claims 17 and 18 as peritoneal fluid, pleural fluid and bronchial washings are excluded from the independent claims.

4. The rejection of claims 1-16 under 35 U.S.C. 103(a) as being unpatentable over Katopodis (US 5,045,453) in view of Gernez-Rieux et al (Pathologie et Biologie, 1963, Vol. 11, pp. 729-741) is maintained for reasons of record. Applicant argues that given the separate disclosures of Katopodis and Gernez-Rieux et al one of skill in the art would not be motivated to determine the level of sialoprotein in the sputum of patients having cancer. However, the rejection stated on page 4, that It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to use the method of Katopodis for the determination of sialoprotein in sputum of patients having bronchitis and asthma, not cancer, as this is not a specific embodiment of claims 1-16..

5. The rejection of claims 1-16 under 35 U.S.C. 103(a) as being unpatentable over Katopodis (US 5,045,453) in view of Bellahcene et al (British Journal of Haematology, 2000, Vol. 111, pp.

1118-1121) is maintained for reasons of record. Rejection of newly added claim 19 is made for the same reasons of record. Applicant argues that the combination of Applicant argues that the combination Katopodis and Bellahcene et al does not render obvious the instant invention as Katopodis et al does not specifically teach the high speed centrifugation step and the washing of the upper layer and that Bellahcene et al uses cell culture and cytology techniques. This has been considered but not found persuasive. Firstly, it is within the purview of one of skill in the art to optimize parameters such as centrifugal speed and the washing of a layer in order to separate a component of a mixture. Secondly, in response to applicant's arguments against the references individually, i.e. the cell culture and cytology techniques of Bellahcene et al, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

6. The rejection of claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katopodis (US 5,045,453) in view of Figarella-Branger et al (Cancer Research, 1990, Vol. 50, pp. 6364-6370) or Rao et al (Trans All-India Institute of Mental Health, 1969, Vol. 9, pp. 35-38) is withdrawn in light of applicant's arguments.

7. The rejection of claim 17 under 35 U.S.C. 103(a) as being unpatentable over Katopodis (US 5,045,453) in view of Bellahcene et al (British Journal of Haematology, 2000, Vol. 111, pp. 1118-1121) is withdrawn in light of applicants amendment.

8. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claim 1 to read on "high" speed centrifugation. The term "high" in claim 1 is a relative term which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite

degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.


9. All other rejections and objections as set forth in Paper No. 4 are withdrawn.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
October 21, 2002


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